

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF VERMONT**

**PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA,**

*Plaintiff,*

**v.**

**JULIE AREL, in her official capacity as  
Interim Commissioner of Health for the  
State of Vermont,**

*Defendant.*

**No.** \_\_\_\_\_

**Judge:** \_\_\_\_\_

**COMPLAINT FOR DECLARATORY AND PRELIMINARY AND PERMANENT  
INJUNCTIVE RELIEF**

1. Recently enacted Vermont House Bill 266 (“H.B. 266”), to be codified at 18 VT Stat., chapter 91, subchapter 6, violates the United States Constitution’s Supremacy Clause and Due Process Clause. Plaintiff Pharmaceutical Research and Manufacturers of America (“PhRMA”) brings this Complaint and states as follows:

### **PRELIMINARY STATEMENT**

2. H.B. 266 is Vermont’s attempt to rewrite the terms of a federal program known as the 340B Drug Pricing Program, 42 U.S.C. § 256b (“340B”). The substance and subject of the state law is unabashedly a federal drug pricing program reflecting a delicate, carefully calibrated balance struck by the United States Congress. State laws that attempt to rework that federal program are preempted. *Pharm. Rsch. & Mfrs. of Am. v. Morrissey*, 760 F. Supp. 3d 439, 453-60 (S.D. W. Va. 2024) (preliminary enjoining state 340B statute as likely preempted); *cf. Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011) (holding common law remedy displaced because Congress trusted federal agency alone with administration of 340B).

3. 340B was enacted in 1992 as a unique form of privately funded federal subsidy. It requires that drug manufacturers make an “offer” to sell certain of their drugs to 15 statutorily enumerated types of healthcare providers (“covered entities”) at “strikingly generous” prices—often “penn[ies] per unit.” *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024); 42 U.S.C. § 256b(a)(1), (4). Covered entities, in turn, are limited in what they can do with 340B-priced drugs: By statute, they are barred from selling *or* transferring 340B-priced drugs to anyone other than their patients, which is known as “diversion.” 42 U.S.C. § 256b(a)(5)(B).

4. Congress could not outright mandate these penny-price sales by manufacturers—doing so would invite constitutional challenge. Instead, Congress struck a specific bargain with drug manufacturers reflecting a careful balance of interests: If drug manufacturers agree to make a bona fide *offer* to sell certain drugs at 340B prices to covered entities, those drugs would also be

eligible for reimbursement under Medicare Part B and the federal share of Medicaid. Otherwise, they would not. As two federal Courts of Appeals have made clear, Congress’s chosen “offer” framework permits drug manufacturers to impose reasonable conditions on the offers they are required to make to covered entities. *See Novartis*, 102 F.4th at 460-61; *Sanofi Aventis U.S. LLC v. U.S. Dep’t of Health & Human Servs.*, 58 F.4th 696, 703-06 (3d Cir. 2023). Under fundamental principles of contract law, if covered entities accede to those conditions, they accept the terms of the offer and may purchase 340B-priced drugs. *See Williston on Contracts* § 6:11 (4th ed.) (“Thus, if an act is requested [as part of an offer], that very act and no other must be performed.”). If covered entities reject the conditions, the offer is rejected and no purchase of the 340B-priced drugs occurs. *Williston on Contracts* § 6:11 (“[B]ecause the offeror is entitled to receive what it is it has bargained for, if any provision is added to which the offeror did not assent, the consequence is . . . that the offer is rejected, and that the offeree’s power of acceptance thereafter is terminated.”).

5. To incentivize continued participation and maintain uniformity, Congress authorized the U.S. Secretary of Health and Human Services, superintended by federal courts, to administer and enforce 340B through a range of carefully balanced and exclusive federal mechanisms. 42 U.S.C. § 256b(d). Those mechanisms include a unique administrative dispute resolution (“ADR”) scheme run by the U.S. Health Resources and Services Administration (“HRSA”), an agency within the Department of Health and Human Services (“HHS”). *Id.* Congress intended HHS to “hold the control rein” to ensure that 340B would be administered “harmoniously on a uniform, national basis.” *Astra USA, Inc.*, 563 U.S. at 120. The Supreme Court ruled that this enforcement mechanism was the exclusive remedy for disputes about the

operation of 340B. *Id.* at 119-22. In so holding, it found that third-party suits to enforce the law were incompatible with the statutory regime. *Id.* at 120.

6. At the heart of this litigation is an effort to protect the integrity and viability of 340B by honoring the bounds and measures Congress set for the program. Congress created 340B to help underserved patient populations of covered entities. But in recent years, 340B has become a lucrative moneymaker for national pharmacy chains, who are not supposed to benefit from the program, and others who seek to enrich themselves at the expense of these underserved patients.

7. Over the past decade, concerns about diversion and illegal “duplicate discounts” in the 340B program have skyrocketed as covered entities have teamed up with so-called “contract pharmacies”—mostly for-profit pharmacies—nationwide to find ways to maximize the volume of 340B drug price reductions. Under the now prevailing product “replenishment model,” contract pharmacies first order drugs at market prices, and then, following sale of those drugs, seek to replenish their inventories with 340B-priced drugs by retroactively identifying, via black-box algorithms, drugs that are purportedly eligible for 340B pricing.

8. As a result, the volume of drugs purchased at reduced 340B pricing has exploded. In 2023, discounted 340B purchases reached a record *\$66.3 billion*, a \$12.6 billion increase from 2022 and a \$61 billion increase from 2010. Those 2023 purchases reflect manufacturer-provided discounts of *\$57.8 billion* from market rates. *Id.* Almost no 340B price reductions are passed on to patients. *See IQVIA, Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, <https://tinyurl.com/3d4tk9ae>.

9. The United States Government Accountability Office (“GAO”) and the HHS Office of the Inspector General (“OIG”) have warned about the risks of abuse created by the use of contract pharmacies and the product replenishment model. Manufacturers, including many

PhRMA members, have identified specific concerns and independently adopted policies to address them. Although the exact contours of the policies differ, they are all intended to curb abuse, and generally (1) provide a limit on the number of outside pharmacies with which a covered entity may contract to receive 340B-priced drugs, such as “one contract pharmacy policies,” and (2) require the contract pharmacy to submit data supporting their claims for the 340B-priced drugs, generally referred to as “claims data policies,” as a condition precedent to receiving 340B-priced drugs.

10. Both the D.C. and Third Circuits have held that, under federal law, these types of policies are reasonable and permissible conditions drug manufacturers may impose on the 340B offers they make to covered entities. *Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 703-06. Specifically, to help prevent unlawful diversion of 340B drugs, manufacturers can include a condition that they will deliver 340B-priced drugs to the covered entity itself or, if the covered entity lacks an in-house pharmacy, one designated “contract pharmacy.” *Novartis*, 102 F.4th at 460-64; *id.* at 456-58 (explaining how covered entities’ use of an “unlimited” number of contract pharmacies materially changed the nature of the program and substantially inflated the volume of 340B-priced drugs); *Sanofi*, 58 F.4th at 704 (“Congress’s use of the singular ‘covered entity’ in the ‘purchased by’ language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies.”).

11. Similarly, those same two federal appellate courts have held that, under federal law, manufacturers can lawfully include conditions requiring covered entities to provide certain details regarding the prescriptions on which they sought 340B pricing, known as claims data. *Novartis*, 102 F.4th at 463 (affirming *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783, at \*4 (D.D.C. Nov. 5, 2021); *Sanofi*, 58 F.4th at 701. This information is critical to

determining whether a 340B prescription qualifies for 340B pricing and, if not, to access the federal enforcement regime for redress.

12. If a covered entity, or a contract pharmacy purporting to act on its behalf, does not accept an offer with those conditions, there is no qualifying 340B “purchase” under 42 U.S.C. § 256b(a)(1), and therefore no obligation on manufacturers to provide 340B pricing.

13. In response to adverse federal court decisions interpreting the federal 340B statute, covered entities’ representatives have turned to the states, including Vermont, arguing that states can bar the very same conditions that federal law expressly permits these manufacturers to impose.

14. This type of meddling in a purely federal program is preempted. As one court has already held, laws that wrest enforcement control over the federal program from the federal government by imposing a state enforcement regime and that preclude collection of claims data violate the Supremacy Clause. *Morrisey*, 760 F. Supp. 3d at 453-60 (holding that the Supreme Court in *Astra* “has already found that such attempts to enforce 340B are contrary to law”).

15. Those conclusions equally apply to H.B. 266. In multiple ways, it purports to change the requirements of the federal 340B program and the conditions under which manufacturers provide their drugs at reduced prices. That attempted alteration of federal requirements violates the Supremacy Clause.

16. **First**, the law explicitly prohibits manufacturers from undertaking actions that are fully permissible under federal law and that can be imposed as conditions as part of the manufacturers’ offer of 340B-priced drugs, as determined by multiple federal courts. 18 VT Stat. § 4682(a). For example, whereas Congress categorically *did not* require manufacturers to provide 340B-priced drugs to unlimited numbers of contract pharmacies, H.B. 266 mandates it. In doing so, H.B. 266 seeks to compel transactions at the 340B price where they would not otherwise occur

under federal law. That not only violates the federal statute, but also fundamentally alters the bargain struck by Congress for manufacturer participation in 340B, which is reflected in agreements between manufacturers and the federal agency.

17. **Second**, it breaks the federal remedial regime by essentially hiding from manufacturers details on 340B-priced drugs that are dispensed and by explicitly limiting manufacturers' federal audit rights. *Id.* § 4682(b) (barring manufacturers or their agents from “directly or indirectly requir[ing] a 340B covered entity to submit any claims, utilization, encounter, purchase, or other data as a condition for allowing the acquisition of a 340B drug by or delivery of 340B drug to a 340B contract pharmacy”). Under the federal regime, manufacturers must first audit a covered entity before initiating ADR and must also show good cause to the federal agency in order to initiate that first-step audit. H.B. 266 directly interferes with that process by hiding from manufacturers the very information needed to initiate audits.

18. **Third**, it prohibits manufacturers from adopting alternative pricing mechanisms, such as a “cash replenishment model,” “cash-rebate model,” or “credit model,” that will provide greater transparency. These models are already in use for certain types of covered entities with the federal government's blessing and ensure manufacturers can comply with overlapping statutory commands.<sup>1</sup> 18 VT Stat. § 4682(d) (requiring manufacturers to provide “340B drug pricing to a 340B covered entity or 340B contract pharmacy in the form of a discount at the time of purchase” and not “in the form of a rebate”).

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<sup>1</sup> A cash replenishment, cash-rebate, or credit model may vary by manufacturer, but generally work as follows: Entities first buy manufacturer medicines at commercial prices, as they do under the current product replenishment model. After identifying a prescription as 340B-eligible, a covered entity submits a rebate claim to the manufacturer electronically. The manufacturer then issues a rebate representing the difference between the commercial price and the 340B price. That method is faster, simpler, and more transparent, and it gives a manufacturer the information needed to restore the 340B statute's guardrails.

19. **Finally**, H.B. 266 impermissibly intrudes on the exclusive federal enforcement regime that Congress established. H.B. 266 attempts to open the same door for private suits to enforce federal 340B requirements that the Supreme Court explicitly slammed shut in its unanimous 2010 opinion in *Astra*. *See id.* § 4684(a).<sup>2</sup> As the Supreme Court explained, Congress “authorized no private right of action under § 340B for covered entities who claim they have been charged prices exceeding the statutory ceiling” and that bar cannot be circumvented by “dress[ing] their claims” in other “clothing.” *Astra*, 563 U.S. at 113-14.

20. In addition, as the Supreme Court’s *Astra* opinion also makes clear, Congress in 2010 chose to address a series of 340B disputes between healthcare providers and drug manufacturers by creating a detailed series of federal remedial provisions, administered by the federal agency. The agency itself has concluded that those federal remedies would address exactly the same issues H.B. 266 seeks to regulate. 89 Fed. Reg. 28,643, 28,649 (Apr. 19, 2024). Yet Vermont believes it can create its own competing enforcement regime. As the U.S. Supreme Court already explained in *Astra*, “recognizing [covered entities’] right to proceed in court could spawn a multitude of dispersed and uncoordinated lawsuits by 340B entities,” wresting control from the federal government and creating “substantial” “risk of conflicting adjudications.” 563 U.S. at 120. Among other things, a Vermont decisionmaker will need to decide multiple questions of federal law before imposing liability for a suit brought by a private entity or Vermont officials. 42 U.S.C. § 256b(a)(4)-(5). If Vermont and other states are permitted to render decisions on these core

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<sup>2</sup> Vermont’s own Deputy Commissioner of Insurance flagged concerns around this private right of action, stating the Department “cannot support the provisions of H.266 that give covered entities and their contract pharmacies a private right of action to enforce the law.” Letter from Emily Brow, Vermont Deputy Commissioner of Insurance to House Comm. on Health Care 2-3 (Mar. 7, 2025), <https://tinyurl.com/5423ashz>.

federal issues, the uniform federal program will cease to be federal or uniform, again contradicting the Supreme Court’s reasoning in *Astra*.

21. H.B. 266’s penalties also conflict with the carefully balanced provisions in the federal statute. H.B. 266 imposes a penalty of up to \$100 per violation, with “[e]ach package of 340B drugs” constituting a separate violation, and authorizes private rights of action. 18 VT Stat. § 4684; *id.* §§ 7-8. These potential penalties and the private rights of action will transform 340B into something Congress never intended. Drug manufacturers may decide to opt out of key federal programs as a result, defeating the carefully balanced purposes of 340B entirely. *See Astra*, 563 U.S. at 120; *see also Novartis*, 102 F.4th at 462 (noting federal government’s argument that 340B’s “enforcement scheme is carefully calibrated, which tends to suggest that it is exclusive”).

22. H.B. 266 attempts to regulate in an exclusively federal field and, worse, directly conflicts with the federal statute. It is accordingly both field and conflict preempted under the Supremacy Clause.

23. H.B. 266 also violates the Constitution’s Due Process Clause. H.B. 266’s broad prohibitions on “interference” provides no discernible standard by which manufacturers could conform their conduct or that would constrain enforcement, violating basic principles of due process.

24. PhRMA brings this action to declare unlawful this improper state intrusion into the federal 340B scheme and to enjoin preliminarily and permanently Defendant from seeking to enforce H.B. 266 against PhRMA’s members in connection with the sale of their drugs.

### **PARTIES**

25. PhRMA, a trade association representing the nation’s leading innovative biopharmaceutical research companies, advocates for policies that encourage the discovery and development of important new pharmaceutical products.

26. PhRMA's members, which manufacture and sell pharmaceutical products, participate in the federal 340B program and will thus be forced to supply their drugs at a steeply reduced price under H.B. 266 or otherwise face significant civil repercussions, via penalties and private rights of action.

27. Neither the claims asserted nor the relief sought in the Complaint requires the participation of any individual member of PhRMA.

28. Defendant Julie Arel is the Interim Commissioner of Health for the State of Vermont and is sued in her official capacity. The Commissioner is responsible for overseeing the provisions of H.B. 266 and for reporting any violation for prosecution. 18 VT Stat. § 4684; *id.* §§ 7-8. The Commissioner has her principal office in this district at 280 State Drive, Waterbury, VT 05671-8300.

### **JURISDICTION AND VENUE**

29. PhRMA's causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 1343(a)(3).

30. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

31. This Court has inherent equitable powers to enjoin the actions of state officials if they contradict the federal Constitution or federal law. *Ex parte Young*, 209 U.S. 123, 159-60 (1908); *accord, e.g., Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

32. Venue is proper in this district because this action challenges a Vermont law applicable to the sale of PhRMA's members' drugs in this district, and thus H.B. 266 purports to directly restrict and restrain PhRMA members' conduct in selling and distributing drugs within this district. 28 U.S.C. § 1391(b)(2).

33. Substantial amounts of PhRMA’s members’ drugs are sold under the 340B program to covered entities in this district. For example, HHS’s website reflects that there are numerous covered entity sites in the District of Vermont. *See* HRSA, Covered Entity Search Criteria, <https://340bopais.hrsa.gov/coveredentitysearch>. The same HHS website reflects that those covered entities maintain a substantial number of contract pharmacy arrangements, including with contract pharmacies in this district. Accordingly, H.B. 266 is likely to be enforced against PhRMA members in this district.

34. Venue is also proper in this district because Defendant maintains her principal office in this district. 28 U.S.C. § 1391(b)(1).

### **BACKGROUND**

#### **A. The History of 340B**

35. Congress established 340B in 1992 to restore drug discounts that had been provided voluntarily by manufacturers to a select group of safety-net providers before Congress passed the Medicaid Drug Rebate Program (“MDRP”) in 1990. Indeed, Congress carefully restricted the list of eligible 340B covered entities to certain enumerated types of entities that “provide direct clinical care to large numbers of uninsured Americans.” H.R. Rep. No. 102-384, pt. 2, at 12 (1992) (“House Report”).

36. Prior to the enactment of 340B, drug manufacturers had offered discounts on certain outpatient drugs on a voluntary basis to direct healthcare providers like covered entities, but not to pharmacies. *See* Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-And-A-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol’y 25, 29-30 (2019) (“Prior to the MDRP, drug manufacturers regularly offered discounts to . . . hospitals and other safety net providers”). When Congress passed the MDRP in 1990, that law took the manufacturers’ previous *voluntary* “large discounts” to safety net providers like covered entities

and factored it into the calculation of *required* “best price” for purposes of determining Medicaid rebates. *Id.* at 29-30. The “unintended consequence” of this pricing “snafu” was that drug manufacturers were “disincentivized” from continuing to provide the voluntary discounts they had provided to safety net providers prior to the MDRP’s passage. *See id.*; *see also* H.R. Rep. No. 102-384, pt. 2, at 9-10 (1992).

37. Congress created 340B to address the limited problem created by the MDRP’s enactment, specifically to restore the discounts that were previously offered voluntarily by manufacturers. *See* Pub. L. No. 102-585, 106 Stat. 4943, 4962; *see also* House Report at 12. When Congress passed 340B, the legislative history indicates that it intended to restore “discounts to these clinics, programs, and hospitals,” i.e., “direct clinical care” entities, which had previously received voluntary discounts. House Report at 12.

38. When it passed the 340B law in 1992, Congress estimated that the Program would only include approximately 90 hospitals, 85 family-planning clinics, 120 AIDS-intervention sites, 54 AIDS drug purchasing assistance programs, a network of hemophilia treatment centers with 150 facilities, and 2,225 health centers that qualified to participate. *Id.* at 13.

## **B. The Operation and Growth of 340B**

39. 340B has grown dramatically in the intervening years.

40. In 2023, 340B purchases reached a record \$66.3 *billion*, a \$12.6 billion increase from 2022 and a \$61 billion increase from 2010. Adam J. Fein, *The 340B Program Reached \$66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA’s Curious Actions*, Drug Channels (Oct. 22, 2024), <https://tinyurl.com/59ckpy5w>; Karen Mulligan, Ph.D., *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, Univ. of S. Cal. (Oct. 14, 2021), <https://bit.ly/3FFSemV>. There has been no similar increase in the relevant underserved patient populations that could explain this explosive growth.

41. With the list price value (*i.e.*, based on wholesale acquisition cost) of 340B purchases rising to \$124.1 billion in 2023 alone, Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to \$124B in 2023* 6, IQVIA (2024), 340B has become the second largest government pharmaceutical program, exceeded only by Medicare Part D. Adam J. Fein, *The 340B Program Reached \$54 Billion in 2022—Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023), <https://tinyurl.com/44yz9b3d>.

42. 340B is supposed to be governed by a federal statutory framework. Under 340B, participating manufacturers “*shall offer*” to each “covered entity” (as delineated by the federal 340B statute) certain outpatient drugs (also specified by statute) at or below a price (again set by statute), *if* such drugs are offered to any other purchasers, meaning manufacturers must make a genuine offer to covered entities for purchase of 340B-priced drugs. 42 U.S.C. § 256b(a)(1). That requirement does not involve an obligation to provide 340B-priced drugs to an unlimited number of contract pharmacies.

43. Federal law defines “covered entity” for purposes of 340B to mean an entity that “is one of” 15 types of specifically enumerated categories of healthcare providers, 42 U.S.C. § 256b(a)(4), and that meets other specifically enumerated requirements, including that the entity does not engage in an unlawful transfer of 340B-priced drugs and does not seek or cause a duplicate Medicaid discount. 42 U.S.C. § 256b(a)(5).

44. Federally Qualified Health Centers, children’s hospitals, critical access hospitals, sole community hospitals (*i.e.*, hospitals geographically isolated from other hospitals, 42 U.S.C. § 1395ww(d)(5)(D)(iii)), and certain other clinics and hospitals are all specifically defined as “covered entities” eligible to enroll and participate in 340B. 42 U.S.C. § 256b(a)(4); *see also Am.*

*Hosp. Ass’n v. Azar*, 967 F.3d 818, 820-22 (D.C. Cir. 2020). Retail pharmacies are not among the listed covered entities.

45. Federal law defines the “ceiling price” for purposes of 340B to mean “the maximum price that covered entities may permissibly be required to pay for the drug.” 42 U.S.C. § 256b(a)(1). That ceiling price is deeply reduced compared to the drug’s market price.

46. Manufacturers must “offer” their covered outpatient drugs at or below the applicable “ceiling price” to “covered entities,” and only “covered entities” may receive this pricing under the express terms of federal law. *See id.*

47. Identifying the specific obligations imposed by 340B’s “shall offer” provision on drug manufacturers requires the interpretation of 42 U.S.C. § 256b(a)(1). According to courts that have reviewed this question to date, a drug manufacturer must provide some meaningful path for covered entities to obtain these medications at the 340B price. *See* 42 U.S.C. § 256b(a)(1); *Novartis*, 102 F.4th at 462-64; *Sanofi*, 58 F.4th at 703. But the statute does not mandate a commitment to provide 340B-priced drugs to an unlimited number of contract pharmacies of a covered entity’s choosing. *Novartis*, 102 F.4th at 461 (“The requirement to ‘offer’ drugs at a certain ‘price’ does not prohibit distribution conditions, much less require the offeror to accede to any distribution terms demanded by the offeree.”); *see also Sanofi*, 58 F.4th at 703.

48. The 340B statute, in turn, forbids covered entities from “resell[ing] or otherwise transfer[ring]” a covered outpatient drug “to a person who is not a patient of the entity,” 42 U.S.C. § 256b(a)(5)(B), demonstrating that 340B is intended to be a closed system.

49. Manufacturers “opt into” 340B by signing a uniform federal contract with HHS “for covered drugs purchased by 340B entities.” *Astra*, 563 U.S. at 113. That uniform contract is known as the “Pharmaceutical Pricing Agreement” (“PPA”). *Id.* at 117. PPAs do not vary between

manufacturers, but “simply incorporate statutory obligations and record the manufacturers’ agreement to abide by them.” *Id.* at 118.

50. If HHS determines that a manufacturer breached its 340B obligations, HHS can terminate the PPA and remove the manufacturer from the 340B program. *See* 42 U.S.C. § 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412-13 (Dec. 12, 1996). And if the manufacturer is removed from the 340B program, its medicines, will no longer be eligible to receive reimbursements under Medicaid and Medicare Part B, which would have a profound impact on many vulnerable patient populations. *See* 42 U.S.C. § 1396r-8(a)(1), (a)(5), (b)(4)(B)(v).

51. Given the stakes for Medicare Part B and Medicaid and their patient populations, Congress chose to assign oversight and enforcement responsibilities exclusively to HHS to ensure the delicate balance that maintains manufacturer participation. HHS, in turn, has delegated 340B’s oversight and enforcement to its component agency, HRSA. Neither the 340B statute nor any federal regulations promulgated under it authorize, envision, or create room for state regulation of the 340B program. Indeed, the Supreme Court made that clear in *Astra*, holding that the administration and enforcement provisions established an exclusive system of federal management designed to be “harmoniously” administered on a “nationwide basis,” with HHS “hold[ing] the control rein.” *Astra*, 563 U.S. at 120.

52. Congress carefully specified the exclusive mechanisms available for administering 340B disputes and violations: audits, ADR, and an enforcement scheme directed by HHS. For instance, the statute specifies that manufacturers have a right to audit covered entities to ensure that the covered entity is complying with the 340B program’s requirements. 42 U.S.C. § 256b(a)(5)(C). Manufacturers, in turn, are also subject to compliance audits. *Id.* § 256b(d)(1)(B)(v).

53. The imposition of penalties for violating 340B is directly committed to HHS: HRSA evaluates manufacturers' compliance with the 340B statute's requirements and may seek to have HHS impose civil monetary penalties of up to \$7,000 on manufacturers that purposefully charge covered entities more than the statutory 340B ceiling price for covered outpatient drugs. 42 U.S.C. § 256b(d)(1)(B)(vi) (\$5,000, adjusted for inflation). "Overcharging" refers to charging a covered entity a price above the applicable 340B "ceiling price."

54. 340B also provides for resolving 340B disputes between manufacturers and covered entities via an ADR process to be established through "[r]egulations promulgated by the Secretary [of HHS]." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 826-27 (2010) (codified at 42 U.S.C. § 256b(d)(3)) (amending the statute to require HHS to promulgate regulations establishing ADR).

55. These regulations must "designate or establish a decision-making official or decision-making body within [HHS] to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price . . . and claims by manufacturers that violations of [statutory prohibitions on unlawful transfers of 340B drugs and duplicate discounts] have occurred." *Id.* (codified at 42 U.S.C. § 256b(d)(3)(B)(i)); *see* 42 C.F.R. § 10.20 (setting out requirements for ADR review panels).

56. HRSA regulations also must be designed with such safeguards and "procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii).

57. To ensure finality and repose, the statute provides that “administrative resolution of a claim or claims . . . shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.” *Id.* § 256b(d)(3)(C).

58. Federal regulations issued in 2024 make clear HRSA’s view that it has federal statutory authority to address issues regarding manufacturer contract pharmacy policies, including through ADR. *See* 89 Fed. Reg. 28,643, 28,649 (Apr. 19, 2024) (defining overcharge to encompass “a claim that a manufacturer has limited the covered entity’s ability to purchase covered outpatient drugs at or below the 340B ceiling price or the manufacturer does not offer the 340B ceiling price”). In other words, the federal government believes it has authority to address the same precise subject matter H.B. 266 purports to regulate. *Id.*; 42 U.S.C. § 256b(d)(1) (covering “overcharges and other violations of the discounted pricing requirements”).

59. Covered entities must also comply with requirements under 340B. As explained above, covered entities are prohibited from “resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the entity.” *Id.* § 256b(a)(5)(B) (prohibiting unlawful transfers). Covered entities are also prohibited from seeking or causing unlawful “duplicate discounts or rebates” from manufacturers. *Id.* § 256b(a)(5)(A). Such “duplicate discounting” most often occurs when a covered entity obtains a drug at the 340B price and dispenses it to a Medicaid patient, and the manufacturer then also pays a Medicaid rebate to the state Medicaid agency on the same drug. A covered entity that engages in unlawful transfers or duplicate discounting, which would violate § 256b(a)(5), no longer qualifies as a covered entity under the federal statute. *Id.* § 256b(a)(4) (specifying that to qualify as a covered entity, the entity must “meet[] the requirements described in paragraph (5)”). Whether a healthcare entity qualifies as a “covered entity” is a decision entrusted to the federal government.

### C. Contract Pharmacy Abuses

60. As noted above, 340B requires that a manufacturer offer 340B pricing only to a “covered entity.” 42 U.S.C. § 256b(a)(1).

61. Retail pharmacies are not “covered entit[ies],” so they are ineligible to receive 340B pricing.

62. But certain private, for-profit entities—including the largest national chain pharmacies—have, in increasing numbers, sought to leverage 340B as a tool to enhance their profitability in a way that Congress never intended. This is typically accomplished through complicated contractual arrangements between a covered entity, a pharmacy, and other entities like a third-party administrator.

63. The core feature of these arbitrage arrangements is that the for-profit pharmacies end up obtaining drugs purchased at the 340B price. These contract pharmacies, however, serve not only patients of 340B covered entities, but the general public as well—despite the fact that 340B-priced drugs are legally permitted to be dispensed only to patients of 340B covered entities. Inevitably, and at great financial benefit to themselves, contract pharmacies sell drugs purchased at 340B prices to patients who are ineligible to receive such 340B-priced drugs. Contract pharmacies also reap financial benefit when they dispense to 340B-eligible patients: by extracting dispensing fees and a portion of the 340B “spread” (the difference between the 340B price and what payers reimburse them for the drug), for-profit pharmacies divert value Congress intended to go to covered entities and their patients.

64. Between 2010 and 2018, the number of such contract pharmacy arrangements with covered entities exploded, increasing “more than fifteen-fold, from about 1,300 to approximately 20,000 [as of 2018].” GAO., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 10 (2018) (“2018 GAO Report”),

<https://tinyurl.com/mr4xbp2m>. A more recent study put the increase between 2010 and 2020 at 4,228%, with now “more than 27,000 individual pharmacies (almost one out of every three pharmacies)” participating in 340B as contract pharmacies. Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program* 4, Berkeley Rsch. Grp. (Oct. 2020), <https://tinyurl.com/3rk5v8nu>. By 2020, each covered entity used an average of 22 contract pharmacies. *Id.* at 7. As a result, the number of actual claims for 340B discounts nationwide *tripled* between 2014 and 2019. *See* Adam J. Fein, *New HRSA Data: 340B Program Reached \$29.9 billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020), <https://tinyurl.com/5n7bmw5m>.

65. Several federal watchdogs, including the GAO and HHS’s own OIG, have warned that the growth of these arrangements exacerbates concerns about abuse and unlawful claims for 340B drugs. *See* 2018 GAO Report at 44 (“The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities’ current oversight practices.”); *id.* at 45 (“The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts.”).

66. Here is how the system has evolved over recent years: Under the product “replenishment model” now in widespread use by contract pharmacies,<sup>3</sup> the pharmacies sell drugs from their general inventories to all individuals (both 340B covered entity patients and non-340B covered entity patients)—at prices significantly above the 340B price. *See Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the S. Comm. On Health, Educ.*

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<sup>3</sup> A recent U.S. Senate report confirmed: “With the rise of contract pharmacy use in the 340B Program, most covered entities now use the virtual inventory/product replenishment model to dispense 340B drugs.” U.S. Sen. Comm. On Health, Educ., Lab. & Pensions, 119th Cong., *Congress Must Act To Bring Needed Reforms To The 340B Drug Pricing Program* 31 (Apr. 2025), <https://tinyurl.com/yurm3fey>.

*Labor, & Pensions*, 115th Cong. 11 (2018) (statement of Ann Maxwell, Assistance Inspector Gen. for Evaluation & Inspections, OIG) (“Maxwell Testimony”) (“[M]any contract pharmacies dispense drugs to all of their customers—340B-eligible *or otherwise*—from their *regular* inventory.” (emphasis added)), <https://tinyurl.com/5n8jdr9n>.

67. Then, after subsequent data analysis using undisclosed algorithms, the contract pharmacies purport to retroactively identify individuals with some relationship to a covered entity—purported covered entity “patients” who were not previously identified as covered entity “patients” at the time the drug was dispensed. *Novartis*, 102 F.4th at 457 (noting that the third-party administrators who run these algorithms “often receive a larger fee for every prescription deemed eligible for the discount”).<sup>4</sup> These black-box algorithms likely result in contract pharmacies claiming prescriptions as 340B-eligible where the individual who was dispensed the drug is not a covered entity “patient.” See HHS OIG, Mem. Report: Contract Pharmacy Arrangements in the 340B Program OEI 05-13-00431 16 (Feb. 4, 2014), <https://bit.ly/3eWKmBQ>.<sup>5</sup> This process operates in an “after-the-fact” manner inconsistent with the specific program guidance published by HRSA. Although that guidance provides that each prescription be verified as 340B eligible at the time of drug dispensing, no prescriptions are verified in this manner under the product replenishment model. See 61 Fed. Reg. 43,549, 43,556

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<sup>4</sup> See, e.g., 2018 GAO Report at 2; Maxwell Test. at 11.

<sup>5</sup> HHS OIG has acknowledged this problem. It discussed the following hypothetical: a physician, who practices part-time at a covered entity hospital, gives a prescription to a patient at his private practice. See Maxwell Test. at 11. Although this prescription would likely not qualify for 340B, see 80 Fed. Reg. 52,300, 52,306 (Aug. 28, 2015), one contract pharmacy said it would claim a 340B price because it simply matches the name of the prescriber with those who work at a 340B covered entity *at all* (even if only part time), see Maxwell Test. at 11. This demonstrates how contract pharmacies can expand the definition of an eligible “patient” to cover additional, non-340B prescriptions. See also *Novartis*, 102 F.4th at 458 (remarking on this very issue).

(Aug. 23, 1996); *see Novartis*, 102 F.4th at 457 (“Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount.”).<sup>6</sup>

68. The pharmacies then purchase additional drugs at the 340B price—nominally in the name of the covered entities—to “replenish” the drugs sold previously to the purported covered entity patients. Again, this is done after the fact, without the benefit of data verifying that these retroactively reduced prescriptions were actually 340B eligible.

69. Once those replenishment drugs are received, the cycle starts anew: the 340B-priced drugs are again commingled in the pharmacy’s general inventory and dispensed to any individual who walks in the door, regardless of covered entity patient status. Decl. of Krista M. Pedley ¶ 11, *Sanofi-Aventis U.S., LLC v. U.S. Dep’t of Health & Human Servs.*, No. 21-cv-00634-PGS-JBD (D.N.J. June 24, 2021), ECF No. 93-2 (HRSA Director of Office of Pharmacy Affairs stating that under the product replenishment system, contract pharmacies use stock replenished at 340B prices as “neutral inventory” that “may be dispensed to any subsequent patient”).

70. On information and belief, supported by publicly available information, covered entities *do not* retain title to the drugs throughout the process, and contract pharmacies *do not* act as agents of covered entities and instead serve as independent contractors at most. *See, e.g.*, Walgreens Contract §§ 3.3.5, 8.10, *Sanofi-Aventis U.S. LLC v. HHS*, No. 24-cv-1603 (D.D.C. Nov. 29, 2024), ECF No. 24-2 (showing contract pharmacies take title to the 340B drugs and do not operate as agents of covered entities); Dallas County, 340B Contract Pharmacy Services

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<sup>6</sup> This is one reason why purchases of 340B-priced drugs have grown tremendously, while the number of patients treated by covered entities has not. *See* William Smith & Josh Archambault, *340B Drug Discounts: An Increasingly Dysfunctional Federal Program* 5, PIONEER HEALTH (Mar. 2022), <https://bit.ly/3MShVog>.

Agreement – ReCept Pharmacy at 5 (Comm’rs Ct.) (“County shall purchase 340B Drugs through a written contract with the Supplier and shall hold title to such drugs from the time the Supplier fills the order from ReCept [(the contract pharmacy)] made on behalf of the County until the time that ReCept takes delivery of the drugs.”), <https://tinyurl.com/4wm5d9fd>; *see also* Pharmacy Services Agreement Between the County of Monterey and CVS Pharmacy, Inc. at 9, <https://tinyurl.com/yr72mhup>.

71. Indeed, on information and belief, covered entities do not even know beforehand that a contract pharmacy or a third-party administrator is submitting an order for 340B-priced drugs nominally in its name.

72. As is evident, the product replenishment model seeks to lower the price of drugs for commercial pharmacies and covered entities, not patients—by seeking to replenish contract pharmacy inventories with 340B-priced drugs. There is no dispute that the pharmacies could replenish their inventories by ordering the drugs at market prices, but they instead attempt to do so at 340B prices.

73. On information and belief, the majority of Vermont contract pharmacies operate using the product replenishment model.

74. This product replenishment practice can provide a windfall for covered entities and pharmacies. *See* GAO, GAO-20-108, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* 5 (2019) (explaining that covered entities “purchase [340B-priced] drugs at the 340B Program price for all eligible patients regardless of the patients’ income or insurance status” and “receiv[e] reimbursement from patients’ insurance that may exceed the 340B prices paid for the drugs”), <https://tinyurl.com/bxpnc3ry>. As the D.C. Circuit noted, “[t]he covered entity, the pharmacy, and the third-party administrator [who

runs the algorithms referenced above] often divvy up the spread between the discounted price and the higher reimbursement rate.” *Novartis*, 102 F.4th at 457. Accordingly, “[e]ach of these actors . . . has a financial incentive to catalog as many prescriptions as possible as eligible for the discount.” *Id.* at 457-58.

75. Both CVS and Walgreens, two of the largest for-profit pharmacy retailers, have publicly disclosed that 340B profits are material to their finances. *See* CVS, SEC Form 10-K at 23 (2024), <https://tinyurl.com/4pbtt9x8>; Walgreens, SEC Form 10-K at 30 (2024), <https://tinyurl.com/zp9vv465>; *see also* S. Comm. on Health, Educ., Lab., & Pensions, Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program 26-27 (Apr. 2025) (reflecting CVS’s third-party administrator, Wellpartner, generated \$1.6 billion in revenue from covered entities from 2019 to 2023 through third-party administrator fees), <https://tinyurl.com/3rh429c9>.

76. By contrast, patients routinely do not receive the benefit of the discount in the form of lower prescription costs. *See* Summ. J. Hr’g Tr. at 60:2-7, *PhRMA v. Murrill*, No. 6:23-cv-00997, ECF No. 78 (June 7, 2024) (Counsel for covered entity Intervenor: “Under replenishment, . . . the pharmacy is not going to know that that’s a 340B eligible patient. That’s not in the record the pharmacy has available.”); Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?* 3, 12, IQVIA (2022) (concluding that “most 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts” and that stakeholders in the 340B program, such as contract pharmacies, are “profit[ing] from 340B revenue”), <https://tinyurl.com/mvuy8276>; Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to \$124B in 2023* 6, IQVIA (2024) (“If a substantial number of states pass [policies prohibiting the use of contract pharmacy restrictions], it could

further accelerate 340B growth in the coming years” and “reignite the problem of duplicate discounts, since it is difficult to determine the 340B status of prescriptions that are filled at contract pharmacies.”), <https://tinyurl.com/y9aeb727>.

77. Recent evidence continues to reinforce these conclusions. For example, media reporting has revealed how in many cases 340B price reductions are not passed on to vulnerable populations in the form of lower prices. See Anna Wilde Matthews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients*, WALL ST. J. (Dec. 20, 2022) (explaining that many hospitals do not pass on 340B discounts to their patients and that 340B appears to bolster profits in well-off areas more than helping hospitals in less-privileged neighborhoods), <https://tinyurl.com/bdhhzdhr>; Katie Thomas & Jessica Silver-Greenberg, *How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. TIMES (Sept. 24, 2022) (explaining how one hospital “nakedly capitaliz[ed] on” 340B to turn a profit), <https://tinyurl.com/28ubr4hd>; Joseph Walker, *Employers Get Big Drug Discounts Through Program for Hospitals That Serve Poor Patients*, WALL ST. J. (Mar. 15, 2025) (explaining how sophisticated middlemen help employers tap 340B to save money on prescription drug programs, a far cry from the program’s original focus on aiding low-income patients), <https://tinyurl.com/y34ctaf5>.

78. Similarly, a recent GAO report surveying hospitals found that, of the 30 hospitals surveyed that reported use of contract pharmacies, almost half (14) indicated that they do not provide *any* discounts at contract pharmacies, 10 reported they provide discounts at some contract pharmacies, and only six provided discounts at all contract pharmacies. GAO, GAO-23-106095, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* 16 (2019), <https://tinyurl.com/49jzmnne>. Even among

those that do provide discounts, most (10) reported that it varied by pharmacy or patient circumstances, three reported using the patient's co-pay as the "discount," two reported that they charged more than the 340B price the hospital paid, and only one reported charging less than the 340B price. *Id.* at 17.

79. Other state level reports similarly demonstrate that covered entities and their contract pharmacies provide little financial benefit to vulnerable populations. A 2024 report from North Carolina's treasurer focusing on North Carolina's State Health Plan and purchased oncology drugs found that 340B hospitals applied an average markup of 5.4 times their discounted acquisition costs compared to the 2.9 times markup applied by non-340B hospitals. N.C. Treasurer, *Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program* 14-15 (2024), <https://tinyurl.com/26cxtzw4>. And while North Carolina's 340B hospitals reported an average 15.5% net profit margin compared to the 9.4% profit margin for non-340B hospitals, some of the hospitals reporting the lowest levels of charity care were 340B hospitals and 15.6% of 340B hospitals spent less than 1% on charity care. *Id.* at 19-20.

80. This unlawful and unauthorized expansion of the federal 340B subsidy has other repercussions as well. Expanding the subsidy has led to increased consolidation in the healthcare system, with large hospital beneficiaries snapping up smaller physician providers with "no evidence of hospitals using the surplus . . . to invest in safety-net providers, provide more inpatient care to low-income patients, or enhance care for low-income groups in ways that would reduce mortality." Sunita Desai, Ph.D. & J. Michael McWilliams, M.D., Ph.D., *Consequences of the 340B Drug Pricing Program*, 378 NEW ENG. J. MED., 539, 546 (2018), <https://tinyurl.com/nhhtyyah>.

81. Besides taking 340B price reductions intended for vulnerable populations, the explosion in contract pharmacy arrangements has also led to an increase in unlawful transfers of drugs purchased at a 340B price. *See, e.g.*, 42 U.S.C. § 256b(a)(5)(B) (prohibiting transfer or sale to anyone “who is not a patient of the [covered] entity”); GAO, GAO-11-836, *Drug Pricing, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28 (2011) (“Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies.”), <https://tinyurl.com/yc2mhbeu>. Indeed, approximately two-thirds of violations for unlawful transfers uncovered by HRSA audits “involved drugs distributed at contract pharmacies.” 2018 GAO Report at 44.

82. The use of contract pharmacies can also exacerbate unlawful “duplicate discounting.” 42 U.S.C. § 256b(a)(5)(A). Unlawful duplicate discounting forces the manufacturer to provide a discount on its drug twice-over—once under 340B to the covered entity, and again in the form of a rebate to the state Medicaid agency.

83. GAO has found that duplicate discounting happens with outsized frequency when covered entities use contract pharmacies. *See, e.g.*, 2018 GAO Report at 45; *see generally* GAO, GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (2020), <https://tinyurl.com/mr38ccjr>. As the GAO explains, this is because of the difficulty of auditing and obtaining reliable data for covered entities with “complex” networks of contract pharmacies. 2018 GAO Report at 45.

#### **D. Covered Entities’ Repeated Efforts To Expand 340B**

84. Covered entities have repeatedly attempted to circumvent federal authority over 340B to impose their own preferred obligations on 340B manufacturers.

85. In 2006, covered entities filed suit against several pharmaceutical manufacturers, claiming that they had been overcharged for 340B-priced drugs in violation of the PPAs between manufacturers and the federal government. *Astra*, 563 U.S. at 116-17. In 2009, on review, the Supreme Court unanimously rejected such private actions as an alternative 340B enforcement mechanism, emphasizing the need for 340B to be uniformly administered with an eye toward implications for other federal healthcare programs. *Id.* at 120. As the Supreme Court held, “Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities.” *Id.* at 117. Rather than allowing “340B entities to launch lawsuits in district courts across the country,” with the attendant “risk of conflicting adjudications,” “Congress directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers.” *Id.* at 120-21. “Congress thus opted to strengthen and formalize HRSA’s enforcement authority, to make the new adjudicative framework *the proper remedy*[.]” *Id.* at 121-22 (emphasis added).

86. Approximately ten years later, with the continued explosion in contract pharmacy arrangements, the increased use of the product replenishment model and documented problems with program integrity, certain PhRMA members independently adopted new and different policies to address the 340B abuses reported by federal watchdogs. *See, e.g.*, First Am. Compl. ¶¶ 48-52; *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027 (D. Del. Feb. 12, 2021), ECF No. 13.

87. In response, the General Counsel of HHS issued a legal opinion on December 30, 2020, purporting to interpret the 340B statute and declaring that “*to the extent* contract pharmacies are acting as *agents* of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity

no more than the 340B ceiling price for those drugs.” *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 52-53 (D. Del. 2021). Although the Advisory Opinion was subsequently vacated on other grounds, it demonstrated HHS’s understanding that, at a minimum, an agency relationship is required between a covered entity and its contract pharmacy, echoing prior HRSA guidance. 61 Fed. Reg. at 43,550, 43,555 (HRSA 1996 guidance stating that a covered entity without an in-house pharmacy could contract with *one* contract pharmacy to serve as its “agent”).

88. In May 2021, HRSA issued letter decisions to the manufacturers that were implementing policies to address 340B abuses, including PhRMA members.<sup>7</sup> Litigation ensued.

89. In the context of those suits, courts have repeatedly concluded that the scope of manufacturers’ obligations does not encompass offering or providing 340B-priced drugs to an unlimited number of contract pharmacies—one of the requirements Vermont seeks to impose here.

90. The D.C. Circuit in *Novartis* and the Third Circuit in *Sanofi*, considering two of these lawsuits, began their recent analyses by explaining how the federal statute works and how contract pharmacy and claims data policies interact with it.<sup>8</sup>

91. In *Novartis*, one manufacturer was “willing to work with at least one contract pharmacy designated or previously used by the [covered] entity,” so long as the “contract

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<sup>7</sup> See HRSA, 340B Drug Pricing Program, *HRSA Determines Six Pharmaceutical Manufacturers Are in Violation of the 340B Statute*, Health Res. & Servs. Admin., HRSA Letter to AstraZeneca Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, <https://tinyurl.com/2nybf4z2>; HRSA Letter to Lilly USA, LLC Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, <https://tinyurl.com/5xkem3y7>; HRSA Letter to Novartis Pharmaceuticals Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, <https://tinyurl.com/jytw6xd6>; HRSA Letter to Novo Nordisk Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, <https://tinyurl.com/ycxwceaz>; HRSA Letter to Sanofi Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, <https://tinyurl.com/2veh5838>; HRSA Letter to United Therapeutics Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, <https://tinyurl.com/2p85wz8d>.

<sup>8</sup> One appeal remains pending. See *Eli Lilly & Co. v. Becerra*, Nos. 21-3128, 21-3405 (7th Cir.).

pharmacies provide claims data for contract-pharmacy orders.” 102 F.4th at 463. The other manufacturer “intend[ed] to deliver section 340B drugs to a covered entity’s in-house pharmacy or to a single contract pharmacy designated by the covered entity.” *Id.* at 463-64. In *Sanofi*, two manufacturers permitted the use of “one contract pharmacy” if the covered entity “d[id] not have an in-house pharmacy.” 58 F.4th at 701. A third manufacturer similarly permitted the use of “one contract pharmacy” if the covered entity “d[id] not have an in-house pharmacy,” but also permitted the use of “an unlimited number of contract pharmacies” if the covered entity “agree[d] to provide claims data.” *Id.*

92. 340B requires that manufacturers “offer each covered entity covered outpatient drugs for purchase’ at or below a specified ceiling ‘price.” *Novartis*, 102 F.4th at 460 (quoting 42 U.S.C. § 256b(a)(1)). The covered entity who receives such an “offer” can then accept the terms of the offer and “purchase” the covered outpatient drugs, or they can decide to not “assent to the same terms” and thus reject the 340B offer. *Id.* (quoting 1 *Corbin on Contracts* § 1.11 (2023)); *see also Sanofi*, 58 F.4th at 703 (holding that manufacturers are required to only “present the drugs [with conditions permitted] for covered entities’ acceptance”). Indeed, that Congressional mandate does not “require the offeror to accede to any distribution terms demanded by the offeree.” *Novartis*, 102 F.4th at 461; *Sanofi*, 58 F.4th at 703 (holding that the word “offer” does not “imply that the offeror must deliver good wherever and to whomever the buyer demands”). Where a covered entity rejects the offer, the manufacturer has fulfilled its 340B duty and there is no 340B purchase to which the 340B ceiling price applies. *See Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 703-04.

93. The D.C. Circuit rejected the assertion that 340B requires manufacturers to provide 340B-priced drugs to an unlimited number of contract pharmacies. *Novartis*, 102 F.4th at 460. As

the D.C. Circuit concluded, Congress chose to impose only certain restrictions on 340B-participating manufacturers—most notably that they make a “bona fide” offer, *i.e.*, that they “propose to sell covered drugs to covered entities at or below a specified monetary amount.” *Id.* Congress’s judgment means that manufacturers remain free to impose “conditions on the distribution of covered drugs to covered entities.” *Id.* at 459-60.

94. And the D.C. Circuit similarly rejected the notion that purported silence allowed for imposition of an unlimited contract pharmacy requirement. As that court noted, purported “silence] about delivery conditions . . . preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions.” *Id.* at 460-61. The court also noted that this silence did not mean that manufacturers have carte blanche as to conditions. *Id.* at 462-63. Instead, Congress carefully circumscribed the obligations it placed on manufacturers, only permitting conditions that would not move offers out of the realm of “bona fide” offers. *Id.* The court expressly left to the federal government adjudication of “more onerous conditions” on offers than the ones before it, reviewed by federal courts. *Id.* at 464.

95. The Third Circuit’s decision in *Sanofi* likewise rejected one of the very same obligations Vermont seeks to impose here. 58 F.4th at 703-04. The Third Circuit noted that “Congress’s use of the singular ‘covered entity’ in the [statute’s] ‘purchased by’ language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker *without mixing in a plethora of pharmacies.*” *Id.* (emphasis added); *id.* at 704 (340B does not “require[] delivery to an unlimited number of contract pharmacies”). The Third Circuit also expressly enjoined the federal government from imposing this requirement. *Id.* at 706 (barring the federal government “from enforcing against [plaintiffs] its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies”); *id.* at 704 (noting that

“‘Congress knew how to’ grant covered entities permission to contract with third parties for distribution . . . but did not” (quoting *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 36, 39 (2016))).

96. In doing so, the Third Circuit concluded that, despite the statute’s “silence” as to the number of permitted contract pharmacies, such an unlimited contract pharmacy requirement “overstepped the statute’s bounds,” as reflected in 340B’s structure and other considerations. *Sanofi*, 58 F.4th at 707. The Third Circuit left open the possibility, however, that the federal obligation may require that manufacturers offer to deliver 340B-priced drugs to some pharmacies in certain circumstances (for example, a single contract pharmacy where a covered entity lacks its own in-house pharmacy). 42 U.S.C. § 256b(a)(1); *Sanofi*, 58 F.4th at 703-04. Thus, *Sanofi* ultimately recognizes there is no gap in 340B into which states can step—instead the question requires interpretation of federal law, specifically what constitutes a bona fide “offer” under 42 U.S.C. § 256b(a)(1). *Id.* at 705.

97. Two other courts are in accord. The U.S. District Court for the District of Columbia, likewise determined in *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783 (D.D.C. Nov. 5, 2021), and the court of appeals affirmed, *Novartis*, 102 F.4th at 455, that the 340B statute permits drug manufacturers to impose reasonable conditions regarding contract pharmacies as part of the manufacturers’ participation in 340B, including a reasonable limitation on where manufacturers will send 340B-priced drugs. *Novartis*, 2021 WL 5161783, at \*7. In a similar vein, the U.S. District Court for the District of Delaware concluded in *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 58-59 (D. Del. 2021) that Congress chose not to require manufacturers to provide 340B-priced drugs to an unlimited number of contract pharmacies. *AstraZeneca*, 543 F. Supp. 3d at 58-59.

98. The same is true of manufacturers’ conditions on their offers of 340B-priced drugs that require covered entities and contract pharmacies to provide certain claims data related to the prescriptions that were purportedly dispensed as 340B drugs. Courts have concluded that manufacturers may impose such conditions (including to help fulfill statutory audit protections), and that those conditions on a 340B offer satisfy the federal obligation. *See Novartis*, 2021 WL 5161783, at \*8 (holding that, under federal law, manufacturers are permitted to require certain types of data as a precondition of their “offer” of 340B-priced drugs); *id.* (“For its part, [plaintiff manufacturer] convincingly argues that the claims data conditions that it has added to its new 340B policy will enable it to better utilize the anti-fraud audit and ADR procedures that Congress established for manufacturers in Section 340B.”); *Novartis*, 102 F.4th at 463. That leaves covered entities free to accept such offers, along with their terms, or reject them.

99. For their part, covered entities have sought to use the federal ADR mechanism, which is overseen by a panel within HHS, to enforce this purported obligation to provide 340B-priced drugs to any and all contract pharmacies identified by a covered entity. In those proceedings, a group of covered entities alleged that a drug manufacturer “ha[d] violated the 340B statute and regulations by failing to offer covered outpatient drugs at the 340B ceiling price through Petitioner’s contract pharmacy arrangements.” Those entities asked the panel “to order [the manufacturer] to resume offering covered outpatient drugs at the 340B ceiling price to Petitioner through its contract pharmacies; and to order [the manufacturer] to pay Petitioner an amount equal to the 340B discounts that [the manufacturer] has failed to provide.” *Petition for Damages and Equitable Relief ¶ 1, Open Door Cmty. Health Ctrs. v. AstraZeneca Pharms., LP*, ADR ID: 210112-1 (HHS ADR Bd. Jan. 13, 2021), <https://tinyurl.com/2twhwhtc>; *see also* *Petition for Monetary Damages and Equitable Relief ¶¶ 35-37, Univ. of Wash. Med. Ctr. v. AstraZeneca*

*Pharms. LP* (HHS Bd. Sept. 29, 2023) (Petition by a different group of covered entities asserting panel has jurisdiction over contract pharmacy disputes).

100. Recently, an ADR Panel within HRSA adjudicated an ADR petition premised on an alleged 340B overcharge violation and held that manufacturer contract pharmacy policies *do not* constitute a violation of 340B. *See* HRSA ADR Panel, *St. Croix Reg'l Med. Ctr.* Decision Summary (2025), <https://tinyurl.com/3pvw43zd>.

101. Against the backdrop of unfavorable federal outcomes, covered entities turned their sights to lobbying states to seek the very same benefits they are not owed under federal law. They seek to change the federal program by mandating that manufacturers take actions that even the federal agency tasked with 340B's administration and enforcement cannot require.

102. The repercussions of those efforts, if allowed to stand, will be intensified by the recently enacted Inflation Reduction Act ("IRA").<sup>9</sup> The IRA establishes the Medicare Drug Price Negotiation Program, under which HHS is to "negotiate" with manufacturers "maximum fair prices" for certain drugs. 42 U.S.C. § 1320f-3(a). Manufacturers must provide access to selected drugs at the so-called "maximum fair prices," established by HHS, except that they need not provide access to the maximum fair prices when such selected drugs are 340B-eligible and the 340B price is lower than the maximum fair price. *Id.* § 1320f-2(d). That is, manufacturers need not provide both the 340B price and "maximum fair price" on the same selected drug. *Id.* To avoid duplicate discounting, this scheme necessarily requires identifying when a drug subject to the maximum fair price is dispensed as a 340B drug—further demonstrating the "interdependent nature" of Medicare and the 340B program. *Astra*, 563 U.S. at 120.

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<sup>9</sup> Several of PhRMA's members have drugs that are subject to the IRA's Medicare Drug Price Negotiation Program, including Boehringer Ingelheim Pharmaceuticals, Bristol Myers Squibb Company, Astellas, Novo Nordisk, and Merck.

103. The Centers for Medicare and Medicaid Services (“CMS”) has issued final IRA guidance for avoiding duplicate discounting under the Medicare Drug Price Negotiation Program. Under that guidance, a manufacturer bears the burden of determining and verifying whether a “claim for a selected drug is a 340B-eligible claim.” CMS, Medicare Drug Pricing Negotiation Final Guidance (“Final Guidance”) at 60, <https://tinyurl.com/3sx8hmah>; *see also* CMS, Medicare Drug Price Negotiation Program Draft Guidance (“Draft Guidance”), at 48 (A manufacturer must “indicate[] that the claim for [a] selected drug is a 340B-eligible claim and the 340B ceiling price is lower than the [maximum fair price] for the selected drug.”), <https://tinyurl.com/dapyyjyf>. To facilitate the identification of 340B drugs, dispensing entities are encouraged to use claims codes indicating which drugs are dispensed under the 340B program, and to provide prescriber identification information to help manufacturers identify “whether a prescription was written by a prescriber with a high percentage of claims originating from a 340B covered entity.” Draft Guidance at 41; Final Guidance at 45, 57. Commenters noted “that, under the nonduplication approach described by CMS in the draft guidance, [IRA] Manufacturers would likely mandate 340B claims data submission from covered entities.” Final Guidance at 57. “Many commenters strongly opposed CMS allowing for such mandates and stated that, at minimum, CMS should evaluate and regulate the data requirements imposed by [IRA] Manufacturers on covered entities.” *Id.* In response to such comments, CMS stated it “will not prescribe a specific nonduplication approach that [IRA] Manufacturers must follow or impose parameters” on it, and noted in its justification that manufacturers bear the burden for ensuring nonduplication. *Id.* at 57-58.

104. In recent months, some manufacturers, including PhRMA members, have sought to adopt models known as “cash replenishment,” “cash-rebate,” and “credit models.” Although the exact specifics may vary, the models generally work as follows. As with the product

replenishment model, entities first buy manufacturer medicines at commercial prices. After identifying a prescription as 340B-eligible, a covered entity submits a rebate claim to the manufacturer electronically. The manufacturer then issues a rebate representing the difference between the commercial price and the 340B price. These methods are faster, simpler, and more transparent, and give a manufacturer the information needed to restore the 340B statute's guardrails.

105. Considering that context, a federal court recently held that the federal 340B statute “explicitly contemplates a rebate mechanism,” and that the information gathered through use of these models was necessary to determine if impermissible duplication has occurred. *See Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at \*2-4, \*9 n.11, \*12-14 (D.D.C. May 15, 2025).

#### **E. Vermont Enacts H.B. 266 To Impose State-Law Conditions On 340B**

##### **1. H.B. 266's Passage And Requirements**

106. H.B. 266 was signed by the Governor on June 11, 2025.

107. H.B. 266 is targeted at and has the purpose and effect of regulating a federal program. Indeed, H.B. 266 is clear that its regulatory object is the federal 340B program and without that federal program, H.B. 266 would have no independent effect. *See* 18 VT Stat. § 4681(3). H.B. 266 defines “340B drug” as a “drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. § 256b and is purchased by a 340B covered entity.” *Id.*

108. H.B. 266 includes several prohibitions that apply explicitly to manufacturers. It instructs that “[a] manufacturer or its agent” (a) “shall not deny, restrict, prohibit, or otherwise interfere with, directly or indirectly, the acquisition of a 340B drug by or delivery of a 340B drug to a 340B contract pharmacy on behalf of a 340B covered entity unless receipt by the 340B contract pharmacy is prohibited by the U.S. Department of Health and Human Services”; (b) “shall not

directly or indirectly require a 340B covered entity to submit any claims, utilization, encounter, purchase, or other data as a condition for allowing the acquisition of a 340B drug by or delivery of a 340B drug to a 340B contract pharmacy unless the claims or utilization data sharing is required by the U.S. Department of Health and Human Services”; (c) “shall not interfere with the ability of a pharmacy contracted with a 340B covered entity to dispense 340B drugs to eligible patients of the 340B covered entity”; and (d) “shall offer or otherwise make available 340B drug pricing to a 340B covered entity or 340B contract pharmacy in the form of a discount at the time of purchase and shall not offer or otherwise make available 340B drug pricing in the form of a rebate.” 18 VT Stat. § 4682.

## 2. Enforcement

109. H.B. 266 does not acknowledge the limitations on enforcement power that Congress deemed necessary to maintain the 340B program’s delicate balance calibrated by the federal government.

110. A violation of H.B. 266 subjects manufacturers to penalties of up to \$100 per violation, defined as “each package of 340B drugs.” *Id.* § 4684; *id.* § 7. The Commissioner of Public Health is empowered to report violations of the provision for prosecution. *Id.* § 8.

111. H.B. 266 also explicitly creates a private right of action: “340B covered entity, 340B contract pharmacy, or other person injured by a manufacturer’s or its agent’s violation of this subchapter may bring an action in Superior Court for injunctive relief, compensatory and punitive damages, costs and reasonable attorney’s fees, and other appropriate relief.” *Id.* § 4684(a). Put differently, H.B. 266 empowers private actors in Vermont to circumvent the ADR system established by Congress as 340B’s sole enforcement mechanism and to seek remedies, including “punitive damages” that are unavailable in the federal system.

112. These procedures and remedies differ dramatically from, and extend far beyond, the procedures and remedies that the federal government may pursue under 340B. *See, e.g.*, 42 U.S.C. § 256b(d).

113. H.B. 266 expressly predicates its purported addition of a state law obligation on the existence of an underlying federal obligation. 18 VT Stat. § 4681(3), (4).

114. As a result, in any state enforcement proceeding, a state adjudicator will be required to answer multiple questions of federal law to determine if a manufacturer violated H.B. 266. These include, among other things, whether under *federal* law (1) a particular covered entity has permissibly contracted with a contract pharmacy under federal law and has the necessary “principal-agent” relationship required to even arguably comply with federal law, 42 U.S.C. § 256b(a)(5)(A)-(B); (2) the covered entity continues to “hold title” to the 340B-priced drugs throughout all relevant transactions (which does not occur under the prevailing product “replenishment model”); (3) all of the individuals receiving 340B-priced drugs meet the federal definition of a 340B patient; (4) the particular prescriptions at issue qualify for 340B prices; and (5) the 340B price reductions are duplicative of Medicaid rebates applicable to the same prescriptions, *id.* § 256b(a)(5)(A). A state adjudicator will also be required to determine if a covered entity continues to qualify for participation in the federal program. For example, a covered entity that sells or transfers 340B-priced drugs to anyone other than its patients is no longer eligible to receive 340B-priced drugs. *Id.* § 256b(a)(5). Similarly, covered entities violating prohibitions on duplicate discounts are ineligible to receive any 340B-priced drugs. *Id.* § 256b(a)(4)-(5). Under H.B. 266, a Vermont state adjudicator court will be required to make these determinations to adjudicate any purported violation of H.B. 266.

## **CLAIMS FOR RELIEF**

### **CLAIM I**

#### **(Declaratory/Injunctive Relief—Preemption Under the Supremacy Clause of the U.S. Constitution and the Federal 340B Statute)**

115. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

116. Federal law is “the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. Const. art. VI, cl. 2.

117. H.B. 266 is preempted under the Supremacy Clause because it intrudes upon the exclusive field created by 340B and, worse, does so in a way that directly conflicts with the federal statute’s terms and in a manner that is likely to generate conflict between state and federal regulators.

118. Field preemption exists where (1) Congress’s “framework of regulation [is] ‘so pervasive’” that Congress has “left no room for the States to supplement it,” or (2) where there is a “federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.” *Arizona v. United States*, 567 U.S. 387 399 (2012) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

119. Field preemption is especially likely where a state law “‘diminish[es] the [Federal Government]’s control over enforcement’ and ‘detract[s] from the integrated scheme of regulation’ created by Congress.” *Arizona*, 567 U.S. at 402 (quoting *Wisc. Dep’t of Indus. v. Gould Inc.*, 475 U.S. 282, 288-89 (1986)).

120. As the Supreme Court has recognized, Congress created a comprehensive federal program in 340B and centralized control of that program exclusively within HHS to safeguard the delicate balance Congress struck. *See Astra*, 563 U.S. at 120 (noting the “interdependent” nature of 340B with other federal programs). No room exists for state supplantation in this field.

Congress created the exclusively federal field here through enactment of 340B. Unlike some other federal healthcare programs, where Congress has assigned the states significant roles in administering those programs, it chose not to do so here. *See, e.g.*, 42 U.S.C. § 1396a (Medicaid statute providing for state plans); *id.* § 18031 (Affordable Care Act establishing states' ability to set up health benefit plan exchanges).

121. The system crafted by Congress did not impose open-ended obligations on manufacturers. Instead, Congress designed a pervasive and integrated scheme of regulation through creation of a closed and limited system. Congress carefully defined those eligible to receive 340B drugs (enumerated covered entities), set the nature of the benefit (obligation to offer drugs), and imposed limitations on that benefit (to whom covered entities may furnish 340B-priced drugs). Congress spoke in exacting detail because maintaining a delicate balance in the 340B program, given its interconnection with other federal programs, is essential to ensure that the program achieves its purpose without becoming too onerous for manufacturers. Finally, Congress set out an exclusive federal enforcement scheme to maintain the federal programs as a harmonious whole. Each of these features reinforces that the 340B program is an area of dominant federal concern.

122. H.B. 266 nevertheless seeks to directly intrude on this carefully balanced federal program by expanding and materially altering the scope of manufacturers' obligations and rights, and by implementing a competing enforcement regime. That is far more than 340B requires, permits, or contemplates. *Sanofi*, 58 F.4th at 703; *see also id.* at 706 (Third Circuit enjoining the federal government from mandating part of what Vermont is now attempting to do).

123. That intrusion into the field of the operation of 340B is made clear by H.B. 266's scope. Vermont pharmacies can freely order any drug available to them at market pricing.

H.B. 266 does not seek to expand access to drugs generally—it merely seeks to compel 340B pricing for drug orders. In doing so, Vermont attempts to forcibly insert itself into an arena occupied exclusively by the federal government (i.e., 340B’s reticulated scheme setting forth who can receive 340B-priced drugs). But the federal 340B scheme leaves no room for state supplementation. H.B. 266’s imposition of additional obligations and a separate enforcement scheme is accordingly preempted as an impermissible intrusion into a federally dominated field.

124. H.B. 266 is also conflict preempted. Conflict preemption arises when “[state] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), or “interferes with the methods by which the federal statute was designed to” achieve those purposes and objectives, *Int’l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) (state law preempted because it would “upset[] the balance of public and private interests so carefully addressed by the [federal statute]”). A conflict exists between the 340B statute and federal PPAs, on the one hand, and H.B. 266, on the other, for several reasons.

125. H.B. 266 disregards and conflicts with careful limitations in the federal regime, designed to maintain the delicate balance struck by Congress. As to covered entities, Congress sharply limited what they could do with 340B-priced drugs, prohibiting covered entities from reselling or transferring them to anyone other than their own patients. 42 U.S.C. § 256b(a)(5)(B). As to manufacturers, 340B requires only that manufacturers “offer” 340B-priced drugs to covered entities (i.e., that they provide some meaningful path for covered entities to access these medications). *See id.* § 256b(a)(1); *Novartis*, 102 F.4th 460-64; *Sanofi*, 58 F.4th at 703. The offers can include reasonable conditions, including both one contract pharmacy restrictions and a requirement that claims data be provided. *Novartis*, 2021 WL 5161783, at \*8 (holding that, under

federal law, manufacturers are permitted to require certain types of data as a precondition of their “offer” of 340B-priced drugs); *id.* (“For its part, [the plaintiff manufacturer] convincingly argues that the claims data conditions that it has added to its new 340B policy will enable it to better utilize the anti-fraud audit and ADR procedures that Congress established for manufacturers in Section 340B.”); *Novartis*, 102 F.4th at 463-64 (affirming holding); *Sanofi*, 58 F.4th at 704. As those decisions make clear, other types of conditions would also be permissible so long as they do not render an offer non-bona fide. Finally, Congress provided for an exclusive enforcement regime, which includes (among other things), the right of manufacturers to audit a covered entity. 42 U.S.C. § 256b(a)(5)(C).

126. H.B. 266’s rewriting of the federal program’s terms conflicts with the 340B statute in multiple ways and so is preempted. To name just a few, non-exhaustive examples:

127. *First*, H.B. 266 reworks manufacturers’ obligations under the federal program. Vermont is now seeking to impose as a matter of state law a bar on restrictions on contract pharmacy use, a requirement even the federal government has been enjoined from levying. *Sanofi*, 58 F.4th at 706; *see also Novartis*, 102 F.4th at 463-64 (explaining these reasonable conditions can be included as part of a manufacturer’s 340B offer). By rewriting the terms of the required federal offer and barring manufacturers from including this condition, H.B. 266 dramatically expands manufacturers’ obligations under a federal program. As courts have recognized, this expansion of obligations under a federal incentive program is preempted. *Forest Park II v. Hadley*, 336 F.3d 724, 732-33 (8th Cir. 2003) (holding states may not impose additional obligations on participants in incentive-based, federal programs, even where the federal statute does not explicitly bar such additional obligations). Vermont’s efforts both conflict with the plain text of 340B’s requirements

and stand as an obstacle to the carefully circumscribed and federally managed closed system Congress created.

128. Nor can H.B. 266 be saved by recasting it as a distribution requirement. Vermont is attempting to regulate who can receive 340B-priced drugs, not drugs in general. No one suggests that manufacturers will not provide market-priced drugs to pharmacies. The aim instead is to force manufacturers to provide those same drugs to those same pharmacies at a lower price. *Morrissey*, 760 F. Supp. 3d at 455-56 (recognizing that similar state statute was actually about forcing manufacturers to provide 340B pricing, not about delivery). Indeed, absent the pricing requirement, Vermont’s law would be meaningless. *See* 18 VT Stat. § 4681(3) (“340B drug” means a “drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. § 256b and is purchased by a 340B covered entity”); *see also id.* § 4681(2) (“340B covered entity” means “an entity participating or authorized to participate in the federal 340B drug pricing program, as described in 42 U.S.C. § 256b. The term includes a 340B covered entity’s pharmacy”).

129. *Second*, H.B. 266’s prohibitions on manufacturers gathering information are preempted. *Id.* § 4682(b). If those limits stand, they will essentially break the federal remedial regime. *See Morrissey*, 760 F. Supp. 3d at 450-53 (holding similar state law that barred collection of claims data was preempted because it conflicted with manufacturers’ 340B audit rights); *Eli Lilly*, 2025 WL 1423630, at \*2-4, \*12-14 (affirming manufacturers’ right to “impose data-reporting conditions on covered entities,” explaining why claims data is important to maintaining program integrity, and requiring federal agency to take it into account when considering how manufacturers can structure their program participation).

130. Under the federal regime, manufacturers must first audit a covered entity before initiating ADR. *See* 42 U.S.C. § 256b(a)(5)(C), (d)(3)(B)(iv). However, manufacturers are only permitted to conduct an audit where they “ha[ve] documentation which indicates there is reasonable cause.” 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). “Reasonable cause” is defined to mean “that a reasonable person could believe that a covered entity may have violated” the prohibition on transfer or sale, or the prohibition on duplicate discounting. *Id.* Accordingly, to even access the audit process to engage in an ADR proceeding, manufacturers must be able to access information that will allow them to determine if reasonable cause exists to suspect a covered entity is violating 340B’s provisions. But Vermont’s comprehensive bar on requesting any such data hides from manufacturers evidence of federal violations and handicaps manufacturers from being able to meaningfully utilize the federal resolution process that Congress provided. *See* 18 VT Stat. § 4682(b) (broadly referring to “claims, utilization, encounter, purchase, or other data”).

131. *Third*, H.B. 266’s requires that a manufacturer “offer or otherwise make available 340B drug pricing to a 340B covered entity or 340B contract pharmacy in the form of a discount at the time of purchase” and prohibits “offer[ing] or otherwise mak[ing] available 340B drug pricing in the form of a rebate.” *Id.* § 4682(d). This provision appears to be aimed at preventing the use of cash replenishment, cash-rebate, or credit models by individual manufacturers. Under those models generally, though specific terms may differ, manufacturers will provide cash rebates when covered entities submit a 340B-rebate claim to the manufacturer, rather than sell the 340B-priced drugs at an upfront reduced price. H.B. 266 attempts to prevent their use despite the federal statute providing for use of rebates and the fact that the federal government has already explicitly blessed use of rebate models for certain covered entities, known as AIDS Drug Assistance Programs. *See* 42 U.S.C. § 256b(a)(1) (“taking into account any *rebate* or discount” (emphasis

added); *see also* 63 Fed. Reg. 35,239, 35,240 (June 29, 1998) (recognizing that use of a rebate option is “consistent with the section 340B rebate program”); *Eli Lilly*, 2025 WL 1423630, at \*9 n.11 (stating that the 340B statute “explicitly contemplates a rebate mechanism” and thus holding that these alternative models are allowed by the federal statute).

132. The permissibility and precise contours of these models under federal law is subject to active litigation, including in the D.C. Circuit, and HRSA itself is scheduled to publish guidance about these models in the coming weeks. *Eli Lilly*, 2025 WL 1423630, at \*13-14; *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir.); *see also* Office of Mgmt. & Budget (“OMB”), Regulatory Review (reflecting that the proposed guidance is currently with OMB for review), <https://tinyurl.com/37ahk282>. Yet, Vermont now seeks to explicitly prevent their use.

133. *Fourth*, H.B. 266’s state-law enforcement provisions conflict with the carefully calibrated system created by Congress to ensure 340B compliance and raise the specter of inconsistent adjudications. *See Morrissey*, 760 F. Supp. 3d at 453-60 (holding similar state law was preempted because it conflicted with 340B’s enforcement regime). H.B. 266 impermissibly attempts to permit private suits to enforce 340B, despite the Supreme Court’s determination that Congress explicitly chose not to permit private rights of action. As the Supreme Court made clear, Congress chose not to authorize private rights of action, which would “undermine the agency’s efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis.” *Astra*, 563 U.S. at 120. Instead of permitting “340B entities to launch lawsuits in district courts across the country,” Congress chose to “create formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits[.]” *Id.* at 121. Despite that, Vermont purports to allow private entities to bring their own suits, creating the same “risk of conflicting adjudications”

that prompted the Supreme Court to hold that private actions were barred no matter if the claims were “dressed” in other “clothing.” *Id.* at 113-14, 120.

134. H.B. 266 also conflicts with Congress’s chosen scheme of exclusive federal oversight for 340B. *See Astra*, 563 U.S. at 113; *see also Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349-50 (2001) (where agency had “a variety of enforcement options that allow it to make a measured response,” greenlighting state-law tort claims would “inevitably conflict with the [agency’s] responsibility to police fraud consistently with [its] judgment and objectives”); *Morrisey*, 760 F. Supp. 3d at 453-60. In *Astra*, covered entities operated by Santa Clara County brought suit to enforce 340B pricing against drug manufacturers directly rather than bringing that issue to HRSA. *See* 563 U.S. at 116-17. Two things happened. First, in response to such disputes, Congress stepped in and amended the 340B statute to add detailed administrative enforcement mechanisms—all to be overseen by HRSA, subject to federal court review. 42 U.S.C. § 256b(d). Second, the Supreme Court ruled against Santa Clara County, explaining that the new federal agency administrative enforcement mechanisms were the “proper remedy” for disputes about the operation of 340B. *Astra*, 563 U.S. at 119-22. The Court stressed repeatedly that it was essential 340B be administered “harmoniously and on a uniform, nationwide basis.” *Id.* at 120.

135. H.B. 266 conflicts with that regime in multiple ways. Like the claims considered in *Astra*, H.B. 266 conflicts with the federal enforcement regime by usurping the federal agency’s unitary enforcement authority. Federal ADR regulations issued in 2024 make clear HRSA’s view that it has federal statutory authority to address the same issues as H.B. 266, including through ADR. *See* 89 Fed. Reg. at 28,649 (defining overcharge claim, to be brought via ADR, to encompass “a claim that a manufacturer has limited the covered entity’s ability to purchase covered outpatient drugs at or below the 340B ceiling price or the manufacturer does not offer the 340B

ceiling price”); *see also supra* ¶ 100 (discussing recent ADR Panel decision on this very topic). In other words, the federal government believes it has authority to address the same issues that H.B. 266 purports to regulate—when and under what terms 340B-priced drugs must be provided. *Id.*; 42 U.S.C. § 256b(d)(1). Yet Vermont seeks to address the very same dispute, *contra* to *Astra*. *Morrisey*, 760 F. Supp. 3d at 453-59.

136. A preview of potential state enforcement proceedings drives the impermissible conflict home. Vermont has tied H.B. 266 to 340B. Accordingly, determining whether a manufacturer violated H.B. 266 requires determining if there was an underlying 340B obligation in the first place. To make the latter determination, a decisionmaker will need to answer several federal law questions, including: (1) whether the drugs are actually covered outpatient drugs under 340B; (2) whether they are eligible for 340B pricing; (3) whether the manufacturer provided the 340B price; (4) whether a covered entity is a 340B covered entity under federal law; and (5) whether there has been diversion or duplicate discounting (which includes determining whether a specific drug was distributed to a covered entity’s “patient”). *See Morrisey*, 760 F. Supp. 3d at 458-59; *Eli Lilly*, 2025 WL 1423630, at \*2 (noting requirements for an individual to qualify as a patient of a covered entity).

137. H.B. 266 also skews the carefully balanced enforcement scheme enacted by Congress. Congress specified certain limited civil penalties that could be levied in limited circumstances. 42 U.S.C. § 256b(d)(1)(B)(vi)(II) (setting a maximum of \$5,000 per violation). Yet, H.B. 266 allows for penalties of up to \$100 for each violation, with “each package of 340B drugs” constituting a separate violation. 18 VT Stat. § 4684(b); *id.* § 7. Moreover, Vermont’s provision of a private right of action by covered entities, contract pharmacies, and any “other person injured,” with its threat of “compensatory *and punitive* damages” subjects manufacturers

to extensive liability not contemplated by Congress. *Id.* §4684(a). The layering on of additional adjudicators and penalties wildly unbalances Congress’s system, and threatens the same inconsistent adjudications identified in *Astra* because Vermont cannot enforce H.B. 266 without adjudicating multiple questions of federal law.

138. *Finally*, H.B. 266 frustrates the “accomplishment and execution of the full purposes and objectives of Congress,” *Hines*, 312 U.S. at 67, in various ways in addition to those described above. For example, by purporting to impose additional, onerous terms on 340B (including terms the Third Circuit has held not even the federal government can impose), H.B. 266 increases the cost of manufacturer participation in the federal Medicare Part B and Medicaid programs. As another example, H.B. 266’s mandates will contribute to duplicate discounts and diversion of 340B drugs to ineligible recipients, both of which the federal scheme forbids. In addition, H.B. 266 conflicts with the federal Medicare Drug Price Negotiation Program by frustrating the disclosure of claims data that is necessary to prevent duplicate discounting with the “maximum fair prices” established under the Inflation Reduction Act. *See* 42 U.S.C. § 1396r-8(a)(5)(C).

139. For all of these reasons and more, H.B. 266 is preempted, and its enforcement should be enjoined.

## **CLAIM II**

### **(Declaratory/Injunctive Relief—Due Process Clause)**

140. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

141. The Fourteenth Amendment’s Due Process Clause provides that no state may “deprive any person of life, liberty, or property, without due process of law.” U.S. Const. amend. XIV, § 1.

142. Under the Due Process Clause, a statute is unconstitutionally vague if “it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits,” *Hill v. Colorado*, 530 U.S. 703, 732 (2000), or fails to “provide explicit standards for those who apply” it to avoid “resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application,” *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972).

143. Where, as here, a statute implicates First Amendment interests, greater specificity is required. *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253-54 (2012) (stricter application of vagueness doctrine is appropriate where statute involves speech in order “to ensure that ambiguity does not chill protected speech”); *Smith v. Goguen*, 415 U.S. 566, 572-73 (1974) (considering First Amendment implications in applying due process vagueness analysis); *Grayned*, 408 U.S. at 109 (“[W]here a vague statute abuts upon sensitive areas of basic First Amendment freedoms, it operates to inhibit the exercise of those freedoms.” (internal quotation marks and citations omitted)). These First Amendment interests include the right to publicize information about unlawful activity, conduct audits, file public complaints, and seek information.

144. H.B. 266 provides that a manufacturer may not “otherwise interfere with, directly or indirectly, the acquisition of a 340B drug by or delivery of a 340B drug to a contract pharmacy on behalf of a 340B covered entity” and “shall not interfere with the ability of a pharmacy contracted with a 340B covered entity to dispense 340B drugs to eligible patients of the 340B covered entity.” 18 VT Stat. § 4682(a), (c).

145. H.B. 266 does not define the term “interfere.” *Cf. Carolina Youth Action Project v. Wilson*, 60 F.4th 770, 786 (4th Cir. 2023) (affirming district court grant of summary judgment to plaintiffs where law prohibited “interfer[ing] with or disturb[ing] in any way or in any place the

students or teachers of any school or college in this State” and noting that “[i]t is hard to know where to begin with the vagueness problems with th[e] statute”); *United States v. Elliot*, No. 2:17-cr-33, 2018 WL 11478272, at \*1, \*3 (N.D. Ga. Aug. 8, 2018) (concluding regulation that prohibited “[a]ny act or conduct by any person which interferes with, impedes or disrupts the use of the project” was unconstitutionally vague as applied); *Corp. of Haverford Coll. v. Reeher*, 329 F. Supp. 1196, 1208-09 (E.D. Pa. 1971) *supplemented*, 333 F. Supp. 450 (E.D. Pa. 1971) (collecting cases where prohibitions on interference were deemed unconstitutionally vague).

146. Manufacturers, including PhRMA’s members, are entitled to publicize information about unlawful transfers or duplicate discounting occurring at particular contract pharmacies or covered entities, to audit covered entities and their records relating to contract pharmacies, to file complaints in the context of the federal system that Congress created, and to seek information regarding, and clarify claims from, covered entities and contract pharmacies. But H.B. 266’s plain language appears to prohibit them from doing so. Uncertainty as to the scope of prohibited conduct and speech—which H.B. 266 presents—is the precise problem with vague laws.

### **PRAYER FOR RELIEF**

PhRMA respectfully prays that this Court:

- a. issue an order and judgment declaring that H.B. 266 is unconstitutional and violates federal law;
- b. issue an order and judgment declaring that H.B. 266’s provisions are unlawful as to PhRMA’s members covered outpatient drugs sold through the 340B Drug Pricing program;
- c. enjoin, preliminarily and permanently, the Commissioner from reporting a violation of 18 VT Stat. § 4682 by PhRMA’s members or any person or entity acting as an

agent of PhRMA's members to any State's Attorney in Vermont or the Attorney General for Vermont;

d. enjoin, preliminarily and permanently, the implementation and enforcement of H.B. 266 against PhRMA's members and members' affiliates, officers, agents, representatives or contractors;

e. enjoin, preliminarily and permanently, the implementation and enforcement of H.B. 266 as to the sale of PhRMA's members' drugs under 340B;

f. award PhRMA costs and reasonable attorneys' fees, as appropriate; and

g. grant any other relief the Court finds just and appropriate.

Dated: June 27, 2025

Respectfully submitted,

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